

Patent

ADJUSTABLE BONE PROSTHESES AND RELATED METHODS

Related Applications

This application is a divisional of co-pending U.S. Application Serial No. 10/041,722, filed on 5 8 January 2002, which claims the benefit of provisional Application Serial No. 60/271,895, filed on 27 February 2001, entitled "Adjustable Head Prosthesis for the Shoulder."

Field of the Invention

10 This invention generally relates to an adjustable mounting assembly and alignment system for a bone prosthesis and related methods.

Background of the Invention

A shoulder joint consists of a ball-and-socket 15 type coupling of the humerus to the scapula. The humerus forms the ball, and the socket is formed at the glenoid cavity of the scapula. Injury or disease to the joint often results in destruction or deterioration of the head of the humerus, leading to pain and a corresponding loss 20 of mobility and function. In such cases, it is often necessary to provide a replacement joint surface, i.e., a prosthesis, for the head of the humerus that mates with the glenoid cavity.

The proper alignment of the prosthesis is 25 generally useful to effective performance of the

replacement procedure. Typically, the position of the mount is adjusted until the desired position is achieved.

The mount is fixed in the desired position and the prosthesis is then secured onto the mount.

5 However, conventional mounts provide only a limited range of adjustment, typically allowing only two degrees of freedom, i.e., linearly along an X-axis and Y-axis. The devices that do have more degrees of freedom require multiple trials and a fixture to be used away
10 from the surgical site for proper alignment of the prosthesis to the humerus.

Further, even upon locking the device in a desired position, conventional mounts may not hold the desired position. This is especially true when force is
15 exerted, e.g., hammering the prosthesis to secure its placement on a mount.

There remains a need for mounting systems and methods that permit a wide range of adjustment of a humeral head prosthesis while enabling the mount, and
20 attached prosthesis, to remain securely fixed in a desired position.

Summary of the Invention

The invention provides various adjustable prostheses and related methods that provide a wide range
25 of adjustment along or about multiple axes. The invention makes possible a straightforward, yet robust way of securing, e.g., a humeral head prosthesis in a desired position and maintaining the prosthesis in the desired position during use.

30 Other features and advantages of the inventions are set forth in the following specification and attached drawings.

Description of the Drawings

Fig. 1 is an exploded view of the components
35 of an adjustable locking mount system that embodies

features of the invention, in which the mounting hub is centric.

Fig. 2 is an assembled perspective view of the system shown in Fig. 1.

5 Fig. 3a is a side sectional view of the assembled components of the system shown in Fig. 2.

Fig. 3b is a view similar to Fig. 3a and illustrating the spherical radii of the stacked washers.

10 Figs. 4a-4e illustrate rotational movement of the cooperating components of the assembled system shown in Fig. 2.

Fig. 5a is a side sectional view of the assembled components of the system shown in Fig. 3 and illustrating the system components in a level position.

15 Fig. 5b is a sectional view as shown in Fig. 5a, illustrating the position of the system components and the movement of the mounting hub and lock washer when the mounting hub is rotated about the x or y axis.

20 Fig. 5c is a sectional view as shown in Fig. 5b, illustrating the procedure of locking the system in a desired position.

25 Fig. 6 is an exploded view of the components of an alternative embodiment of an adjustable locking mount system that embodies features of the invention, in which the mounting hub is eccentric.

Fig. 7 is an assembled perspective view of the system shown in Fig. 6.

Figure 8 is side sectional view of the assembled components of the system shown in Fig. 7.

30 Figs. 9a-9e illustrate rotational movement of the cooperating components of the assembled system shown in Fig. 7.

35 Fig. 10 is an exploded view of an adjustable locking mount system embodying features of the invention incorporated in a shoulder replacement assembly.

Fig. 11 is a perspective view of the assembled components of the system shown in Fig. 10.

Fig. 12a is an enlarged perspective view of the top portion of the trial ring shown in Fig. 10.

5 Fig. 12b is an enlarged perspective view of the bottom portion of the trial ring shown in Fig. 10.

Fig. 13a is an enlarged perspective view of the top portion of the artificial head shown in Fig. 10.

10 Fig. 13b is an enlarged perspective view of the bottom portion of the artificial head shown in Fig. 10, and further illustrating the interior surface of the artificial head.

15 Fig. 14a is an exploded view of the components of an alternate embodiment of a shoulder replacement system embodying features of the invention and viewed from the head to the stem.

Fig. 14b is a view similar to Fig. 14a and viewed from the stem to the head.

20 Fig. 15 is a view similar to Figs. 14a and 14b and illustrating a partially assembled view of the system components.

Fig. 16 is a perspective view of a humerus bone, with a line representing a cut in the ball portion of the humerus made during shoulder replacement surgery.

25 Fig. 17 illustrates a humerus as shown in Fig. 16, illustrating the head cut and removed from the humerus and a bore reamed into the bone.

30 Fig. 18 is a perspective view illustrating a humerus as shown in Fig. 17, and further illustrating the insertion into the bore of a stem carrying an adjustable mount of the present invention.

35 Figs. 19a and 19b are perspective views illustrating a humerus as shown in Fig. 18, and further illustrating a trial ring engaging the mount and being rotated simultaneously with the mount.

Fig. 19c illustrates the trial being and the mount rotated independently of each other.

Fig. 20 illustrates a humerus as shown in Figs. 19a and 19b, illustrating the trial ring being 5 simultaneously tilted with the mount.

Fig. 21 illustrates a humerus as shown in Fig. 20, and further illustrates the procedure of locking the mount in a desired position.

Fig. 22 shows a humerus as in Fig. 21, with 10 the trial ring removed and illustrating the placement of an artificial head onto the mount.

Fig. 23 illustrates a humerus as shown in Fig. 22, with the artificial head placed on the mount and further illustrating the use of a hammer to secure the 15 artificial head on the mount.

Fig. 24a is an exploded view of the components of an alternative embodiment of a shoulder replacement system embodying features of the invention and viewed from the head to the stem.

Fig. 24b is a view similar to Fig. 24a and 20 viewed from the stem to the head.

Fig. 25 is a view similar to Figs. 24a and 24b and illustrating the use and placement of the pivot pin component of the system to secure the bottom insert 25 component onto the stem component.

Fig. 26 is a view similar to Fig. 25 and illustrating the placement of the eccentric mount component onto the bottom insert component.

Figs. 27a-27e are partially assembled views of 30 the system shown in Figs. 24a and 24b and illustrating rotational movement of the partially assembled system.

Fig. 28 is a partially assembled view of the system shown in Figs. 24a and 24b and illustrating the placement of the top insert on the bottom insert.

35 Fig. 29 is a perspective view of the

components of the system shown in 24a and 24b assembled.

Fig. 30a is an exploded view of the components of an alternative embodiment of a shoulder replacement system embodying features of the invention and viewed 5 from the head to the stem.

Fig. 30b is view similar to Fig. 30a and viewed from the stem to the head.

Fig. 31 is a view similar to Figs. 30a and 30b illustrating the use of the pivot pin component to secure 10 the mounting ring and the bottom disk to the stem.

Fig. 32 is a view similar to Fig. 31 and illustrating the placement of the top disc on the bottom disk.

Figs. 33a-33e are views similar to Fig. 32 and 15 illustrating the placement of the head component onto the mounting ring component and further illustrating the rotational movement of the assembled system.

Fig. 34 is a view similar to Figs. 33a-33e and illustrating the locking of the assembled system in a 20 desired position.

Fig. 35a is an exploded view of an alternative embodiment of a shoulder replacement system embodying features of the invention viewed from the head to the stem.

25 Fig. 35b is a view similar to Fig. 35a and viewed from the stem to the head.

Fig. 36 is an exploded view of the bottom and top plate components of the system shown in Figs. 35a and 35b and illustrating the major and minor axes of the top 30 and bottom plates.

Fig. 37 is a partially assembled view of the system shown in Figs. 35a and 35b and illustrating the use of the pivot pin to secure the placement of the bottom plate onto to stem.

35 Fig. 38 is a view similar to Fig. 37 and

illustrating the placement of the top plate on the bottom plate.

Figs. 39a-39e are views similar to Fig. 38 and illustrating rotational movement of the partially 5 assembled system.

Fig. 40 is an assembled view of the system shown in Figs. 35a and 35b.

The invention may be embodied in several forms without departing from its spirit or essential 10 characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

15 **Detailed Description**

Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention that may be embodied in 20 other specific structure. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

25 I. **The Adjustable Locking Mount System**

A. **System 1:**

**Interior Hub Centrally Located with
Respect to Mounting Surface**

Fig. 1 shows the individual components of an adjustable locking mounting system 10A. Figs. 2 and 3a 30 illustrate the system 10A when assembled. As will be described in detail later, the system 10A permits adjustment in three directions or three degrees of freedom (rotational around axes x, y, and z, where the z-axis is represented by the axis of the pivot pin 12) (see

Figs. 4a-4e).

The system 10A comprises the pivot pin 12, at least one slip washer 14, at least one lock washer 16, a mounting hub 18, and a locking screw 20. Each of these 5 components of the system 10A will now be described in detail.

1. System Components

As seen in Fig. 1, the pivot pin 12 is a rigid, generally cylindrical or rod-like member. The 10 pivot pin 12 is convex, e.g., domed, at one end to couple with the mounting hub 18 (see, e.g., Fig. 3a). In a representative embodiment, the arc of curvature is 0.400" diameter (0.200" radius).

In particular, the convex arrangement permits 15 adjustment of the mounting hub 18 by swinging or tilting across the axis of the pivot pin 12 (i.e., rotation about the x-axis and y-axis) as well as by rotating or twisting about the axis of the pivot pin 12 (i.e., rotation about the z-axis) (see Figs. 4a-4e).

As best seen in Figs. 1 and 3, the pivot pin 20 12 has a threaded central bore 26 that serves to receive the locking screw 20. Thus, the pivot pin 12 serves to receive both the mounting hub 18 and the locking screw 20 (see Fig. 3a).

The pivot pin 12 can be made of suitable 25 metal, plastic, or ceramic materials and formed by conventional molding or machining techniques.

As shown in Fig. 1, the mounting hub 18 is a rigid member comprising a mounting surface 24, an 30 interior hub 22, and an exterior pivot surface 28. The center of the mounting hub 18 serves to receive the locking screw 20.

The mounting surface 24 is configured to mate 35 with an object or device being mounted on the hub and therefore can take on a variety of shapes. Thus, the

mounting hub 18 serves as a base for mounting of another object or device. For example, the mounting surface 24 can be circular or geometric. In the illustrated embodiment, the mounting surface 24 is generally 5 circular.

Additionally, the mounting surface 24 can be stepped to further aid in positioning and securing the object or device on the mounting surface 24 (not shown).

In this arrangement, the object or device being mounted 10 would have a complementary stepped surface. The stepped surface provides greater control of any adjustment by permitting adjustment to be in uniform increments and reducing the risk of inadvertent movement. The mounting surface 24 could alternatively be a threaded surface to 15 facilitate engagement with a mating part.

As best illustrated in Fig. 1, the interior hub 22 is open. The bottom surface of the interior hub 22 is configured to conform to the shape of the convex end of the pivot pin 12 and sized to receive the slip 20 washer(s) 14 and lock washer(s) 16. That is, the interior hub 22 permits a slip washer 14 and lock washer 16, or multiple slip washers 14 and lock washers 16, to be alternately stacked upon one another (see Fig. 3a).

As shown in Figs. 1-3a, the exterior pivot 25 surface 28 of the mounting hub 18 is configured to nest on and to conform to the convex end of the pivot pin 12, thus permitting a wider range of motion, as previously described.

As best seen in Fig. 3a, the exterior pivot 30 surface 28 is located centrally with respect to the interior hub 22. Further, the interior hub 22 is centrally located with respect to the mounting surface 24, such that the geometric center of the mounting hub 18 coincides with the center of rotation of the mounting hub 35 18 about the pivot pin 12.

The mounting hub 18 serves to engage and pivot about the pivot pin 12, thus permitting adjustment of the position of the mounting hub 18 with respect to the pivot pin 12, as will be described later. Upon obtaining the 5 desired position, the position of the mounting hub 18 can be locked by use of the locking screw 20, as will also be described in greater detail later.

The mounting hub 18 can be made of any suitable metal or plastic and formed by conventional 10 machining or molding techniques.

As shown in Fig. 1, the system 10A also provides at least one slip washer 14. The slip washer 14 is preferably a rigid annular ring or doughnut-like member. As Figs. 1 and 3a best show, the slip washer 14 15 is configured to conform to the bottom surface of the interior hub 22.

The center of the slip washer 14 serves to receive the locking screw 20. The center of the slip washer 14 is of a diameter only slightly larger than the 20 outside diameter of the locking screw 20. The slip washer 14 also serves to provide a frictional surface, which upon tightening of the locking screw 20, serves to further secure the mounting hub 18 in a desired position.

The slip washer 14 permits the lock washer 16 25 to slide across the surface of the slip washer 14 (see Figs. 5a and 5b). The slip washer 14 is similar in function yet physically different in top and bottom spherical radii from the lock washer 16.

As seen in Fig. 3b, additional washers 14 and 30 16 in the assembly would also have different spherical radii, represented by R1-R5 in Fig. 3b, as they are stacked further from the center of rotation or pivot point on the pivot pin 12. In a representative embodiment, R1 is 0.200, R2 is 0.250, R3 is 0.300, R4 is 35 0.350, and R5 is 0.400.

The radii of the washers 14 and 16 can be varied to accommodate the thickness of the individual washers 14 and 16. Regardless of the thickness or radii of the washers 14 and 16, the washers 14 and 16 are 5 configured to rotate about the same pivot point.

Desirably, as illustrated in Figs. 1 and 3a, a second slip washer 14, similar in function but differing in spherical radii from the first slip washer 14 is placed over the lock washer 16. As illustrated in Figs. 10 5a and 5b, the lock washer 16 is able to slide between the slip washers 14.

In this arrangement, the second slip washer 14 provides an additional frictional surface, which upon tightening of the locking screw 20, serves to further 15 secure the desired position.

The slip washer(s) 14 can be made of any suitable metal or plastic and formed by conventional machining or molding techniques.

As also seen in Fig. 1, the system 10A further 20 provides a lock washer 16. The lock washer 16 is a rigid, annular ring or doughnut-like member similar to the slip washer 14.

As Figs. 1 and 3a best illustrate, the lock washer 16 is configured to conform to the surface of the 25 slip washer 14. This arrangement permits the lock washer 16 to be stacked on top of the slip washer 14.

As in the case of the slip washer 14, the center of the lock washer 16 serves to receive the locking screw 20. The center of the lock washer 16 is 30 also sized larger than the center of the slip washer 14.

That is, the center of the lock washer 16 not only serves to receive the locking screw 20, but also permits the lock washer 16 to pivot about the pivot pin 12.

The lock washer 16 also provides two 35 additional frictional surfaces when sandwiched between

two slip washers 14, which upon tightening of the locking screw 20, serve to further secure the desired position.

As also seen in Figs. 1 and 3a, the lock washer 16 is of a larger diameter than the slip washer 14. This arrangement allows the lock washer 16 to fit over the slip washer 14. In a representative embodiment, the lock washer 16 is sized to approximate or be slightly less than the diameter of the interior hub 22, thereby providing a secure fit of the lock washer 16 within the interior hub 22 and allowing only minimal translation in the x and y axes, yet not restricting z-axis translation of the lock washer 16 within the interior hub 22 and with respect to the axis of the pivot pin 12, as will later be described in detail.

This arrangement secures/couples the lock washer 16 to the interior hub 22 and permits the lock washer 16 to slide with the mounting hub 18 over the slip washer 14 (see, e.g., Figs. 5a and 5b). Thus, the lock washer 16 serves to provide an additional rotational and rocking surface for the mounting hub 18.

Like the slip washer 14, the lock washer 16 can be made of any suitable plastic or metal and formed by conventional molding or machining techniques.

Desirably, as previously noted, a second slip washer 14 similar in function but differing in spherical radii from the first slip washer 14 can be provided. In this arrangement, as seen in Figs. 1 and 3a, the lock washer 16 also serves to receive the second slip washer 14. It will be apparent that any number of slip washers 14 and lock washers 16 can be similarly alternately stacked upon each other and thereby accommodate variations in the depth of the interior hub 22.

As also shown in Fig. 1, the system 10A provides a locking screw 20. The locking screw 20 is a screw that is adapted for passage through the mounting

hub 18, the slip washer(s) 14, the lock washer(s) 16, and the pivot pin 12 when the system is assembled (see Fig. 3a). In inside the diameter of the slip washer 14 is sized to approximate or be slightly larger than the 5 diameter of the locking screw 20. This arrangement secures/couples the slip washer 14 to the locking screw 20 and the pivot pin 12.

As illustrated in Fig. 3a, the locking screw 20 is desirably threaded to fit the threaded bore 26 of 10 the pivot pin 12. As Fig. 5c illustrates, rotation (represented by arrow in Fig. 5c) of the screw 20, e.g., by an Allen wrench 30, advances the screw into the pivot pin 12 to fix the mounting hub 18 in a desired position.

The locking screw 20 can be made of any 15 suitable plastic or metal and formed by conventional molding or machining techniques.

The locking screw 20, when not fully tightened, serves to hold the assembly while the desired position is determined. Tightening of the locking screw 20 compresses the washers 14 and 16, hub 18, and pin 12 together, thereby creating multiple frictional forces between the mating surfaces. These frictional forces and the compression of the screw 20 are what limit movement in the locked position.

25 It will be apparent that the components just described can be used in any combination. For example, plastic slip washers 14 may be alternated with metal lock washers 16.

30 **2. Adjustment of the Orientation of
the Mounting Hub**

The system 10A as previously described enables the mounting hub 18 to be oriented in a variety of directions with respect to the pivot pin 12. The types of movement, and thus the types of adjustments permitted, 35 will now be discussed.

The system 10A permits movement of the mounting hub 18 in at least three rotational directions.

First, as represented by arrows in Figs. 4a-4b, the mounting hub 18 can be rocked or rotated, i.e., tilted, about the x-axis (i.e., side to side rotation).
5 This motion is permitted by the convex surfaces of the pivot pin 12, mounting hub 18, slip washer(s) 14, and lock washer(s) 16.

Second, as represented by arrows in Figs. 4c-4d, 10 the mounting hub 18 can be rocked or rotated, i.e., tilted, about the y-axis (i.e., front to back rotation).

This motion is permitted by the convex surfaces of the pivot pin 12, mounting hub 18, slip washer(s) 14, and lock washer(s) 16.

15 Third, as represented by arrows in Fig. 4e, the mounting hub 18 can be rotated 360° in either a clockwise or counterclockwise direction about the z-axis (i.e., axis of the pivot pin 12).

It is to be understood that the rotational and 20 rocking movements permit adjustment in virtually an infinite number of rotational directions.

B. System 2:

**Interior Hub Eccentrically Located with
Respect to Mounting Surface**

25 **1. System Components**

Fig. 6 shows the individual components of an alternative system 10B providing an adjustable locking mount system. Figs. 7 and 8 illustrate the system 10B when assembled.

30 Like system 10A, the system 10B comprises a pivot pin 12, at least one slip washer 14, at least one lock washer 16, a mounting hub 18, and a locking screw 20.

Also like system 10A, the mounting hub 18 has

an exterior pivot surface 28 that is located centrally with respect to the interior hub 22. In this embodiment, as Figs. 6-8 best show, the interior hub 22 is eccentric with respect to the mounting surface 24, such that the 5 geometric center of the mounting hub 18 does not coincide with the center of rotation of the mounting hub 18 about the pivot pin 12. The eccentric configuration permits a broader range of adjustment.

10 **2. Adjustment of the Orientation of
the Mounting Hub**

15 The system 10B as previously described enables the mounting hub 18 to be oriented in a variety of directions with respect to the pivot pin 12. The types of movement, and thus the types of adjustments permitted, will now be discussed.

The system 10B permits movement of the mounting hub 18 in at least five directions.

20 First, as represented by arrows in Figs. 9a-9b, the mounting hub 18 can be rocked or rotated about the x-axis, as previously described for system 10A.

Second, as represented by arrows in Figs. 9c-9d, the mounting hub 18 can be rocked or rotated about the y-axis, as also previously described for system 10A.

25 Third, as represented by arrows in Fig. 9e, the mounting hub 18 can be rotated up to 360° in either direction about the z-axis, as previously described for system 10A.

30 As best illustrated in Figs. 7 and 8, when the mounting hub 18 includes an interior hub 22 that is eccentric relative to the mounting surface 24, the distance from the pivot pin 12 to the mounting surface 24 increases to a maximum value, depicted as point A1 and then decreases to a minimum value, depicted as point A2.

35 Reorientation or translation of the linear position of point A1 and point A2 with respect to the

pivot pin 12 is possible when the mounting hub 18 is rotated about the z-axis.

- Reorientation of points A1 and A2 with respect to the x-axis provides a fourth degree of freedom.
5 Similarly, reorientation of points A1 and A2 with respect to the y-axis provides a fifth degree of freedom.

It is to be understood that the rotational and rocking movements just described permit adjustment in virtually an infinite number of directions.

- 10 After the desired position is obtained, the locking screw 20 is tightened to secure the mounting hub 18 in the desired position, as previously described for System 10A (see Fig. 5c).

II. Use of the System in Shoulder Replacement

- 15 Figs. 10-23 detail the use of either of the previously-described systems 10A or 10B in shoulder replacement surgery. Desirably, system 10B would be employed, thereby providing the greatest range of adjustment. In the embodiment illustrated in Figs. 10-
20 23, the mount of system 10B is employed.

- The long bone of the upper or proximal arm, as shown in Fig. 16, is known as the humerus 38. The proximal end of the humerus 38 comprises a ball-shaped head 40 that normally nests within the glenoid cavity of
25 the shoulder bone, or scapula.

- Through disease or injury, the head 40 of the humerus 38 can become damaged such that the shape of the head 40 is altered or the head 40 does not fit properly within the glenoid cavity. Such damage typically results
30 in the shoulder joint becoming painful and a corresponding reduction in mobility of the joint.

- Conventional techniques provide for replacement of the head 40 of the humerus 38 with a prosthesis, or artificial head 42. As seen in Fig. 10,
35 the system 10B, comprising a pivot pin 12, a mounting hub

18 (with eccentrically located interior hub 22), slip washers 14, a lock washer 16, and a locking screw 20, can be employed within a shoulder replacement assembly 44 suitable for implantation into a humerus 38. The system 5 10B would permit a physician to mount, position, and secure an artificial head 42.

As shown in Fig. 10, the replacement assembly comprises a stem 46 including tendon attachment holes 50, an assembled system 10B implanted within the stem 46, a 10 trial ring 48, and an artificial head 42. Fig. 11 illustrates the replacement assembly 44 in assembled form.

The stem 46 is a conventional stem 46 suitable for implantation within a humerus 38. The stem 46 15 desirably includes tendon attachment holes 50 that serve to secure attachment of tendons (not shown) to the stem 46.

The stem 46 serves to hold the system 10B. That is, the pivot pin 12 is implanted within the stem 46 20 such that the convex portion protrudes at a pre-selected angle from the stem 46 (e.g., 35°).

The pivot pin 12 can be implanted within the stem 46 by various techniques. In one embodiment, the pin 12 is integrally molded with the stem 46. 25 Alternatively, the pin 12 can be a separate member configured to mate with an existing stem 46. In a representative embodiment, the pin 12 includes a Morse taper, as seen in Fig. 10, configured to mate with a complementary tapered surface within the stem 46. In yet 30 another embodiment, the pin 12 is configured to mate with the stem 46 by threaded engagement (not shown).

As also shown in Fig. 10, a trial ring 48 is 35 desirably provided. The trial ring 48 is a rigid, generally ring-like member having an inner surface 52 and an outer surface 54. The inner surface 52 is desirably

eccentric relative to the outer surface 54. The trial ring 48 can be made of plastic or any other suitable material.

The trial ring 48 is adapted to mate with the 5 mounting hub 18, i.e., the trial ring's 48 inner surface 52 geometry approximates the geometry of the mounting surface 24. In the embodiment illustrated in Fig. 10, the mounting surface 24 is circular and conically tapered and the trial ring 48 has an inner surface 52 that is 10 complementary circular and tapered.

Optionally, the inner surface 52 of the trial ring can be of a geometric or stepped formation adapted to mate with a complementary surface on the mounting surface 24, as previously described (not shown).

15 As shown in Fig. 12a, the outer surface 54 of the trial ring 48 desirably has reference markers 56, e.g., A, B, C, and D, spaced circumferentially around the outer surface 54.

20 Optionally, as also seen in Fig. 12a, the outer surface 54 is tapered or radiused outward toward the bottom of the trial ring 48 for better visualization of the markers 56.

25 In the embodiment illustrated in Figs. 12a and 12b, the outer surface 54 of the trial ring 48 contains knurls 58. The knurls 58 provide for easier grasping of the trial ring 48. Optionally, the outer surface 54 does not contain knurls 58 or the outer surface 54 is otherwise adapted for grasping (not shown). The outside diameter 57 of the trial ring 48 corresponds or is 30 equivalent to the outside diameter of the humeral head 42.

35 The trial ring 48 is adapted to engage the mounting hub 18 and pivot simultaneously with the mounting hub 18. In this arrangement, the reference markers 56 can be utilized for evaluation and recording

of the desired position, as will be described in greater detail later.

As seen in Fig. 10, an artificial head 42 is also provided. The artificial head 42 is a rigid, dome-like member having interior 60 and exterior surfaces 62.

5 The artificial head 42 can be made of stainless steel or other suitable materials.

As best illustrated in Figs. 11 and 13a, the exterior surface 62 is domed to mimic the ball-like head 10 40 of the humerus 38.

As seen in Fig. 13b, the interior surface 60 is recessed and adapted to mate with the mounting surface 24. In the embodiment illustrated in Fig. 13b, the inner surface 60 is circular. Optionally, the interior surface 15 60 can be stepped to mate with a complementary mounting surface 24, as previously described (not shown).

As Fig. 13b also shows, the interior surface 60 desirably has reference markers 56' that are complementary to, i.e., mirror, the reference markers 56 20 on the trial ring 48. This assures that, when complementary markers 56 and 56' on the trial ring 48 and the artificial head 42 are similarly orientated with respect to the mounting hub 18, the position of the artificial head 42 will be the same as the position of 25 the trial ring 48, as will be explained in greater detail later.

Desirably, as in the embodiment illustrated in Fig. 13b, the recessed inner surface 60 of the artificial head 42 is eccentrically located with respect to the outer 30 surface 62.

When used in combination with the eccentrically located interior hub 22 of system 10B, this arrangement provides a "double-eccentric" system. The double-eccentric configuration provides a maximum range of 35 adjustment from O axes offset to up to the maximum axes

offset.

In an alternate embodiment, shown in Figs. 14a-14b and 15, the inner surface 60 of the artificial head 42 is centrally located with respect to the outer surface 62. In this arrangement, an intermediate collar 63 having an interior surface 59 and an exterior surface 61 can be provided.

The interior surface 59 of the collar 63 is eccentrically located with respect to the exterior surface 61 and configured to mate with the mounting surface 24. The exterior surface 61 is desirably configured to mate with the interior surface 60 of the artificial head 42. This arrangement also results in a double-eccentric configuration.

In use, as seen in Fig. 16, the physician makes a cut 65 through the head 40 of the humerus 38 by conventional techniques. Next, as shown in Fig. 17, an interior bore 64 is reamed in the humerus 38 by conventional techniques to prepare the bone for receiving the stem 46.

The stem 46, incorporating the system 10B, is then inserted within the bore 64, as shown in Fig. 18. Tendons can then be attached to the stem 46 using the tendon attachment holes 50 (not shown).

The trial ring 48 is then placed on the mounting hub 18. The eccentric interior hub 22 of the mounting hub 18, together with the eccentric inner surface of the trial ring 48 form a double-eccentric system, as shown in Figs. 19a-19c. As represented by arrows in Figs. 19a and 19b, the trial ring 48 is then rotated simultaneously with the mounting hub 18 until the desired position relative to the cut surface of the humerus 38 is achieved (e.g., center of trial ring 48 is centered with cut surface of humerus 38).

As Fig. 19c shows, the trial ring 48 is also

- 21 -

adapted to rotate independently of the mounting hub 18.

Then, as shown in Fig. 20, the trial ring 48 is tilted (represented by arrows and phantom lines in Fig. 20) with the mounting hub 18 until the desired 5 position relative to the cut is achieved (e.g., parallel to cut).

As seen in Fig. 21, the mounting hub 18 is then secured in the desired position by tightening (represented by arrow in Fig. 21) the locking screw 20, 10 e.g., with an Allen wrench 30.

As also seen in Fig. 21, the physician can then make a mark 66 on the humerus 38 corresponding to the position of a given reference marker 56 on the trial ring 48 when the mounting hub 18 is properly aligned.

15 For example, Fig. 21 illustrates a mark 66 made on the humerus 38 corresponding to the position of reference marker "B" when the trial ring 48 is properly aligned.

20 Next, as illustrated in Fig. 22, the artificial head 42 is then orientated so that the desired reference marker on the interior surface 60 of the artificial head 42 is aligned with the mark 66 previously made on the humerus 38.

25 For example, Fig. 22 illustrates the reference marker "B" on the interior surface 60 of the artificial head 42 being aligned with the mark 66 previously made on the humerus 38.

30 The artificial head 42 is then placed (represented by phantom lines in Fig. 22) on the mounting hub 18 in this desired orientation.

Finally, as shown in Fig. 23, the physician seats and secures the aligned artificial head 42 in place by hitting the artificial head 42 with a hammer 68 to lock the tapers together before placing the artificial 35 head 42 into position within the glenoid cavity.

III. Alternate Mounting Systems

A. Embodiment #1:

Eccentric Mechanism

Figs. 24a-29 detail an alternate embodiment of
5 a shoulder prosthesis mounting system 10C embodying
features of the invention. With reference to Figs. 24a
and 24b, the system 10C comprises a stem 46, a pivot pin
12, a bottom eccentric insert 108, an eccentric mount
110, a top eccentric insert 112, at least one fastener
10 114, at least one guidepin 116, and an artificial head
42.

The stem 46 is a conventional stem suitable
for implantation into a humerus and serves to receive the
pivot pin 12. The pivot pin 12 comprises a ball
15 component 118 and a post component 120. The post 120
extends from the ball 118 and is sized to pass through
the mount 110 and an eccentric opening 122 on the bottom
insert 108 to mate with the stem 46, e.g., by threaded
engagement (see e.g., Fig. 24a) or Morse taper (not
20 shown).

In an alternate embodiment, the post 120 and
the ball 118 are not integral. The post 120 is integral
with the stem 46 and extends from the stem 46. The ball
118 is configured to mate with the post 120, e.g., by
25 threaded engagement, and thus is selectively removable
from the post 120.

In either embodiment, the stem 46 is
configured to carry the post 120 such that the ball 118
protrudes at a pre-selected angle from the stem 46, e.g.,
30 35°. Desirably, a portion of the post 120 remains
exterior to the stem 46, enabling the mount 110 to pivot
freely on the ball 118 (see Fig. 29).

The eccentric opening 122 is of a larger
diameter than the post 120 and sized to permit rotation
35 of the mount 110 about the x, y, and z axes, as will be

described in greater detail later.

As seen in Fig. 25, the ball 118 is a spherical member sized to rest on the eccentric opening 122 of the bottom insert 108. This arrangement allows 5 the ball 118 to serve as a pivot surface permitting adjustment of the eccentric mount 110.

The eccentric mount 110 is a ring-like member having an outer surface 124 and an inner surface 126, as seen in Figs. 24a and 24b. As best illustrated in Fig. 10 24b, the inner surface 126 of the mount 110 is eccentric with respect to the outer surface 124. This arrangement allows the head 42 to be positioned eccentrically with respect to the mount 110. As Figs. 25 and 26 show, the bottom insert 108 has an outer surface 128 adapted to 15 mate with the inner surface 126 of the mount, e.g., by recessed slip fit that is free to rotate.

With reference again to Fig. 26, at least one guidepin 116 extends from the bottom insert 108. In the illustrated embodiment, three guidepins 116 are employed. 20 The guidepins 116 are adapted to pass through complementary guidepin holes 130 on the top insert 112 when the top and bottom inserts 112 and 108 are properly aligned. Thus, the guidepins 116 serve to help align and secure the top and bottom inserts 112 and 108.

25 As best seen in Fig. 24b, the top eccentric insert 112 has a top surface 132 and a bottom surface 134. The bottom surface 134 has an eccentric recessed area 136 configured to mate with the ball 118. The top insert 112 is further adapted to rest on the bottom 30 insert 108.

As best shown in Fig. 26, the bottom and top 35 inserts 112 and 108 each further comprise at least one fastener opening 138 adapted for passage of a fastener 114, e.g., a screw. The fastener 114, when tightened, serves to secure the mount 110 in a desired position by

compressing the top and bottom inserts 112 and 108 together around the ball 118 and the mount 110. The "stacking" arrangement of the top and bottom inserts 112 and 108 serves to maximize the surface area compressed, 5 thereby aiding in securing the mount 110 in a desired position.

The eccentric mount 110 along with the eccentric opening 122 of the bottom insert 108 and the eccentric recessed area 136 of the top insert 112 provide 10 a double-eccentric system.

The artificial head 42 serves as a prosthesis for the head of a humerus, as previously described (see, e.g., Fig. 23). As Fig. 24b shows, the recessed interior surface 60 of the head 42 is desirably concentric with 15 respect to the outer surface 62 and is threaded to mate with the outer surface 124 of the mount. Placement of the head 42 onto the mount 110 secures the head to the mount 110 (see Fig. 28).

The system 10C provides at least five degrees 20 of freedom, thereby allowing a wide range of adjustment in multiple dimensions.

First, as illustrated by arrows in Figs. 27a-27b, the mount 110 can be rocked or rotated, i.e., tilted, about the x-axis (i.e., side to side rotation).

25 Second, as illustrated by arrows in Figs. 27c-27d, the mount 110 can be rocked or rotated, i.e., tilted, about the y-axis (i.e., front to back rotation).

Third, as illustrated by arrows in Fig. 27e, the mount 110 can be rotated up to 360° in either 30 direction about the z-axis.

Fourth and fifth, the double eccentric arrangement permits translation of the linear position of points A1 and A2 with respect to the pivot pin 12 when the inserts 108 and 112 and mount 110 are rotated, as 35 previously described for system 10B (see Figs. 7 and 8).

This action permits translation along the x and y axes.

The double-eccentric configuration serves to maximize the range of translational adjustment possible under the fourth and fifth types of movement.

5 In use, as shown in Fig. 25, the pivot pin 12 is passed through the bottom insert 108 and the mount 110. The pivot pin 12 is then coupled to the stem 46, e.g., by screwing the post 120 into the stem 46. As Fig. 10 26 shows, the top insert 112 is then aligned with the bottom insert 108 by aligning the fastener openings 138 on the top and bottom inserts 112 and 108, the guidepins 116 with the guidepin holes 130, and the recessed area 136 with the ball 118.

15 The position of the mount 110 is then adjusted by rotating or rocking the mount about the x, y, and z axes (see Figs. 27a-27e). The fastener 114 is then tightened to secure the mount 110 in a desired position (not shown). Finally, the head 42 is mounted onto the mount 110 (see Figs. 28 and 29).

20 **B. Embodiment #2:**

Disk Slide Mechanism

Figs. 30a-34 detail another embodiment of a shoulder prosthesis mounting system 10D embodying features of the invention. With reference to Figs. 30a 25 and 30b, the system 10D comprises a stem 46, a pivot pin 12, a mounting ring 140, a bottom disk 142, a top disk 144, an artificial head 42, and a locking tool 146.

The stem is a conventional stem 46 and serves to receive a pivot pin 12, as previously described for 30 system 10C. The pivot pin 12 is similar in configuration to the pivot pin of System 10C. The post 120 is adapted to pass through the bottom disk 142 and the mounting ring 140 to mate with the stem 46, e.g., by threaded engagement.

35 As Fig. 31 shows, the ball 118 is sized to

rest within the bottom disk 142. This arrangement allows the ball 118 to serve as a pivot surface, thereby permitting adjustment of the mounting ring 140.

As best seen in Fig. 30a, the mounting ring 5 140 is comprised of an outer ring 148 having a circular marginal surface and an integrally-formed upstanding inner annular ring 150. The center of the inner ring defines a chamber 152 and includes an opening 154 permitting passage of the post 120.

10 With reference again to Fig. 31, the chamber 152 is configured to receive the bottom disk 142 and the ball 118. The outer surface 156 of the inner ring 150 is desirably configured, e.g., threaded, to mate with the interior surface 60 of the head 42.

15 In the illustrated embodiment, the inner ring 150 is concentric with respect to the outer ring 148. However, the invention also contemplates embodiments in which the inner ring 150 is eccentric with respect to the outer ring 148.

20 As best seen in Fig. 34, the center opening 154 of the mounting ring 140 is of a larger diameter than the diameter of the post 120 and sized to permit translation of the mounting ring 140 about the x and y axes and rotation about the z-axis, as will be described 25 in greater detail later.

As seen in Fig. 30a, the mounting ring 140 desirably has a locking aperture 158. The aperture 158 is a bore that transverses the circumferential margin of the mounting ring 140 and serves to receive the locking 30 tool 146. The locking tool 146 is configured for insertion into the locking aperture 158 and allows rotation of the mounting ring 140 to tighten the head 42 onto the mounting ring 140 (see also Fig. 34).

The bottom disk 142 is a ring-like member 35 having an open center permitting passage of the post 120

and is configured to rest within the chamber 152 and receive the ball 118 (see Figs. 30a-31). It is further configured to receive the top disk 144, as illustrated in Fig. 32.

5 Referring again to Figs. 30a and 30b, the top disk 144 has a top surface 160 and a bottom surface 162. The top surface 160 is desirably flat or otherwise configured to permit compression of the top and bottom disks 144 and 142 upon mounting of the head 42 onto the 10 mounting ring 140. The bottom surface 162 has a recessed area 164 configured to mate with the ball 118. The top disk 144 is further configured to rest on the bottom disk 142 (see also Fig. 32).

15 This stacking arrangement permits compression of the top and bottom disks 144 and 142 as the head 42 is mounted onto the mounting ring 140 and serves to maximize the surface area compressed, thereby securing the mounting ring 140 in a desired position.

20 The artificial head 42 serves as a prosthesis for the head of a humerus, as previously described. As seen in Fig. 30b, the recessed interior surface 60 of the head 42 is desirably concentric with respect to the outer surface 62 of the head 42. The invention also contemplates, however, embodiments in which the interior 25 surface 60 is eccentric. The interior surface 60 of the head 42 is also desirably threaded or otherwise configured to mate with the inner ring 150 of the mounting ring 140.

Similar to system 10C, the system 10D provides 30 at least five degrees of freedom.

First, as illustrated by arrows in Figs. 33a-33b, the mounting ring 140 can be rocked or rotated, i.e., tilted, about the x-axis (i.e., side to side rotation).

35 Second, as illustrated by arrows in Figs. 33c-

33d, the mounting ring 140 can be rocked or rotated, i.e., tilted, about the y-axis (i.e., front to back rotation).

Third, as illustrated by arrows in Fig. 33e, 5 the mounting ring 140 can be rotated up to 360° in either direction about the z-axis.

The difference between the outside diameter of the top and bottom disks 144 and 142 and the inside diameter of recessed chamber 152 forms a gap, as seen in 10 Fig. 32. This arrangement permits linear translation along the x-axis, providing a fourth degree of freedom, and the y-axis, providing a fifth degree of freedom.

In use, with reference to Figs. 30a-32, the post 120 is passed through the bottom disk 142 and the 15 mounting ring 140. The post 120 is then coupled to the stem 46, e.g., by screwing. The top disk 144 is then aligned with the bottom disk 142 by aligning the recessed area 164 with the ball. Next, the head 42 is mounted onto the mounting ring 140.

20 The position of the head 42 is then adjusted by rotating and rocking the head 42 about the x, y, and z axes (see Figs. 33a-33e). As Fig. 34 illustrates, the locking tool 146 is then inserted into the locking aperture 158. As represented by arrows in Fig. 34, the 25 mounting ring 140 is then rotated by use of the locking tool 146 to tighten the head 42 onto the mounting ring 140. This action places all the components in compression and fixes the head 42 in place.

C. Embodiment #3:

30 **Slotted Mechanism**

Figs. 35a-40 detail another embodiment of a shoulder prosthesis mounting system 10E embodying features of the invention. With reference to Figs. 35a and 35b, the system comprises a stem 46, a pivot pin 12), 35 a bottom plate 166, a top plate 168, at least one

fastener 170, and at least one fastening element 172 for securing the fastener 170.

The stem 46 and pivot pin 12 are configured as previously described for systems 10C and 10D. The post 5 120 is adapted to pass through the bottom plate 166 to mate with the stem 46, e.g., by threaded engagement. The ball 118 is sized to rest on the bottom plate 166. This arrangement allows the ball 118 to serve as a pivot surface that permits adjustment of the bottom plate 166.

10 As shown in Fig. 36, the bottom plate 166 is a circular member having a major axis A1 and a minor axis A2. An elongated eccentric slot 174 is provided along the major axis A1. The bottom plate 166 also provides a pair of elongated fixation slots 176 radially spaced from 15 the center and parallel to the major axis A1. The fixation slots 176 allow the position of the top plate 168 to be laterally adjusted with respect to the bottom plate 166. The fixation slots 176 also serve to receive fasteners 170, e.g., bolts, to secure the position of the 20 top plate 168.

As shown in Fig. 37, the eccentric slot 174 receives the ball 118 and allows lateral, i.e., side to side, adjustment (represented by arrows and phantom lines in Fig. 37) of the position of the ball 118 within the 25 eccentric slot 174.

The bottom plate 166 includes a circumferential outer surface 178 configured to mate with the head 42, e.g., by threaded engagement (see e.g., Fig. 35b). The bottom plate 166 serves to receive the top 30 plate 168 in a stacked configuration.

Referring again to Fig. 36, the top plate 168 is a generally elliptical member having a major axis A3 and a minor axis A4. The major axis A3 parallels the minor axis A2 of the bottom plate 166 and the minor axis 35 A4 parallels the major axis A1 of the bottom plate 166

when the top plate 168 is aligned with bottom plate 166.

The top plate 168 further provides fastener receiving openings 180 sized and configured to receive the fasteners 170.

5 The top plate 168 further provides a top surface 182 and a bottom surface 184. The top surface 182 is configured to receive a fastening element 172 for the fastener 170, e.g., a nut. The bottom surface 184 includes a recessed area 186 configured to mate with the
10 ball 118. The recessed area 186 desirably includes an opening 188 adapted for viewing the ball 118, thereby aiding in aligning the top plate 168 with respect to the bottom plate 166. The top plate 168 is further configured to rest on the ball 118, leaving a gap between
15 the top plate 168 and bottom plate 166.

The fasteners 170, when tightened, serve to secure the plates 166 and 168 to the ball 118 in a desired position by compressing the top and bottom plates 166 and 168 together. The stacked arrangement of the
20 plates 166 and 168 serves to maximize the surface area compressed, thereby aiding in securing the plates 166 and 168 in the desired position relative to the ball 118.

The artificial head 42 serves as a prosthesis for the head of a humerus, as previously described. The
25 recessed interior surface 60 of the head 42 is desirably concentric with respect to the exterior surface 62 of the head 42, as shown in Fig. 35b. It should be understood, however, that the invention also contemplates embodiments in which the interior surface 60 is eccentric.

30 Similar to systems 10C and 10D, the system 10E provides at least five degrees of freedom.

First, as illustrated by arrows in Figs. 39a-39b, the bottom plate 166 can be rocked or rotated, i.e., tilted, about the x-axis (i.e., side to side rotation).

35 Second, as illustrated by arrows in Figs. 39c-

39d, the bottom plate 166 can be rocked or rotated, i.e., tilted, about the y-axis (i.e., front to back rotation).

Third, as illustrated by arrows in Fig. 39e, the bottom plate 166 can be rotated up to 360° in either
5 direction about the z-axis.

The slots 176 in the base 166 permit translation of the linear position of the major axis A1 and minor axis A2 with respect to the pivot pin 12 when the bottom plate 166 is slid along the x axis, providing
10 a fourth degree of freedom, or the y axis, providing a fifth degree of freedom.

In assembling the system 10E, the post 120 is passed through the eccentric slot 174 of the bottom plate 166, thereby resting the ball 118 within the slot 174, as
15 seen in Fig. 37. The bottom plate 166 is then slid (illustrated by arrows in Fig. 37) along the slot 174 until the desired lateral position is obtained. The fasteners 170 are then passed through the fixation slots 176 of the bottom plate 166.

20 Next, the top plate 168 is aligned with the bottom plate 166 by aligning the recessed area 186 with the ball 118 and the fastener receiving holes 180 with the fasteners 170. The fasteners 170 are then passed through the fixation slots 176 of the bottom plate 166
25 and the fastener receiving openings 180 on the top plate 168. The top plate 168 is thereby positioned to rest on the ball 118 and over bottom plate 166, as Fig. 38 illustrates. The position of the plates 166 and 168 is then adjusted by rotating or rocking the bottom plate 166
30 about the x, y, and z axes (see Figs. 39a-39e).

The components of the system 10E can be provided in a fully assembled form in which the user only need tighten the fasteners 170 after adjusting the position of the plates 166 and 168 to secure the plates
35 166 and 168 in the desired position.

Fastening elements 172, e.g., nuts, can be used if desired to tighten and secure the fasteners 170.

This action compresses the plates 166 and 168 around the ball 118 to secure the plates 166 and 168 in the desired 5 orientation and location relative to the ball 118.

Finally, as seen in Fig. 40, the head 42 is mounted onto the bottom plate 166.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore, 10 since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed 15 without departing from the invention, which is defined by the claims.